CLAIMS

What is claimed is:

1. A method for delivering a pharmaceutical via an ocular surface of a mammal, the method comprising contacting the ocular surface of the mammal with a mucoadhesive film that comprises:

a water-soluble bioadhesive layer to be placed in contact with an ocular surface, the bioadhesive layer including one or more bioadhesive polymers and/or one or more film-forming, water-soluble polymers;

a water-soluble non-adhesive backing layer that comprises one or more water-soluble, film-forming, pharmaceutically acceptable polymers; and

one or more pharmaceuticals associated with the bioadhesive layer, associated with the non-adhesive layer, or associated with both the bioadhesive and non-adhesive layers;

wherein the mucoadhesive film is compatible with ocular surfaces; the mucoadhesive film adheres to ocular surfaces; the mucoadhesive film is flexible; and the mucoadhesive film is water-soluble, biodegradable, and bioerodible in tear fluids.

2. The method of claim 1 wherein the one or more film-forming water-soluble polymers comprises an alkyl cellulose or a hydroxyalkyl cellulose.

3. The method of claim 1 wherein the one or more film-forming water-soluble polymers comprises hydroxyethyl cellulose (HEC), hydroxypropyl cellulose (HPC), hydroxypropylmethyl cellulose (HPMC), hydroxyethylmethyl cellulose (HEMC), or a combination thereof.

4. The method of claim 1 wherein the one or more film-forming, water-soluble polymers comprises hydroxypropylmethyl cellulose (HPMC).

5. The method of claim 1 wherein the one or more bioadhesive polymers comprise polyacrylic acid (PAA), sodium carboxymethyl cellulose (NaCMC), polyvinyl pyrrolidone (PVP), or a combination thereof.

6. The method of claim 1 wherein the one or more water-soluble, film-forming, pharmaceutically acceptable polymers comprise an alkyl cellulose or a hydroxyalkyl cellulose.

7. The method of claim 1 wherein the one or more water-soluble, film-forming, pharmaceutically acceptable polymers comprise hydroxyethyl cellulose (HEC), hydroxypropyl cellulose (HPC), hydroxypropylmethyl cellulose (HPMC), hydroxyethylmethyl cellulose (HEMC), polyvinylalcohol (PVA), polyethylene glycol (PEG), polyethylene oxide (PEO), ethylene oxide-propylene oxide co-polymers, or a combination thereof.

8. The method of claim 1 wherein the one or more water-soluble, film-forming, pharmaceutically acceptable polymers comprise hydroxyethyl cellulose (HEC), hydroxypropyl cellulose (HPC), or a combination thereof.

9. The method of claim 1 wherein the one or more water-soluble, film-forming, pharmaceutically acceptable polymers comprise hydroxyethyl cellulose (HEC).

10. The method of claim 1 wherein the water-soluble non-adhesive backing layer further comprises a non-water soluble lubrication layer.

11. The method of claim 1 wherein the one or more pharmaceuticals are independently selected from the group of adrenergic agent; adrenocortical steroid; adrenocortical suppressant; alcohol deterrent; aldosterone antagonist; amino acid; ammonia detoxicant; anabolic; analeptic; analgesic; androgen; anesthesia, adjunt to; anesthetic; anorectic; antagonist; anterior pituitary suppressant; anthelmintic; antiacne agent; anti-adrenergic; anti-allergic; anti-amebic; anti-androgen; anti-anemic antianginal; anti-anxiety; anti-arthritic; anti-asthmatic; anti-atherosclerotic; antibacterial; anticholelithic; anticholelithogenic; anticholinergic; anticoagulant; anticoccidal; anticonvulsant; antidepressant; antidiabetic; antidiarrheal; antidiurietic; antidote; anti-emetic; anti-epileptic; anti-estrogen; antifibronolytic; antifungal; antiglaucoma agent; antihemophilic;

antihermorrhagic; antihistamine; antihyperlipidemia; antihyperlipoproteinemic; antihypertensive; antihypotensive; anti-infctive; anti-infective, topical; anti-inflammatory; antikeratinizing agent; antimalarial; antimicrobial; antimigraine; antimycotic, antinausant, antineoplastic, antineutropenic, antiobessional agent; antiparasitic; antiparkinsonian; antiperistaltic, antipneumocystic; antiproliferative; antiprostatic hypertrophy; antiprotozoal; antipruritic; antipsychotic; antirheumatic; antischistosomal; antiseborrheic; antisecretory; antispasmodic; antithrombotic; antitussive; anti-ulcerative; anti-urolithic; antiviral; appetite suppressant; benign prostatic hyperplasia therapy agent; blood glucose regulator; bone resorption inhibitor; bronchodilator; carbonic anhydrase inhibitor; cardiac depressant; cardioprotectant; cardiotonic; cardiovascular agent; choleretic; cholinergic; cholinergie diagnostic aid; diuretic; dopaminergic agent; ectoparasiticide; emetic; enxzyme inhibitor; estrogen; fibrinolytic; flourescent agent; free oxygen radical scavenger; gastrointestinal motility effector; glucocorticoid; gonad-stimulating principle; hair growth stimulant; hemostatic; histamine H2 receptor antagonist; hormone; hypocholesterolemic; hypoglycemic; hypolipidemic; hypotensive; imaging agent; immunizing agent; immunomodulator; immunoregulator; immunostimulant; immunosuppressant; impotence therapy; inhibitor; keratolytic; LNRN agonist; liver disorder treatment; luteolysin; memory adjuvant; mental performance enhancer; mood regulator; mucolytic; mucosal

protective agent; mydriatic; nasal decongestant; neuromuscular blocking agent; neuroprotective; NMDA antagonist; non-hormonal sterol derivative; oxytocic; plasminogen activator; platelet activating factor antagonist; platelet aggregaton inhibitor; post-stroke and post-head trauma treatment; potentiator; progestin; prostaglandin; prostate growth inhibitor; prothyrotropin; psychotropic; radioactive agent; regulator; relaxant; repartitioning agent; scabicide; sclerosing agent; sedative; sedative-hypnotic; selective adenosine A1 antagonist; serotonin antagonist; serotinin inhibitor; serotinin receptor antagonist; steroid; stimulant; suppressant; symptomatic multiple sclerosis; synergist; thyroid hormone; thyroid inhibitor; thyromimetic; tranquilizer; treatment of amyotrophic laterial sclerosis; treatment of cerebral ischemia; treatment of Paget's disease; treatment of unstable angina; uricosuric; vasoconstrictor; vasodilator; vulnerary; wound healing agent; zxanthine oxidase inhibitor; and combinations thereof.

12. The method of claim 1 wherein the one or more pharmaceuticals are selected from the group of Acebutolol; Acebutolol; Acyclovir; Albuterol; Alfentanil; Almotriptan; Alprazlam; Amiodarone; Amlexanox; Amphotericin B; Atorvastatin; Atropine; Auranofin; Aurothioglucose; Benazepril; Bicalutamide; Bretylium; Brifentanil; Bromocriptine; Buprenorphine; Butorphanol; Buspirone; Calcitonin; Candesartan; Carfentanil; Carvedilol; Chlorpheniramine;

Chlorothiazide; Chlorphentermine; Chlorpromazine; Clindamycin; Clonidine; Codeine; Cyclosporine; Desipramine; Desmopressin; Dexamethasone; Diazepam; Diclofenac; Digoxin; Digydrocodeine; Dolasetron; Dopamine; Doxepin; Doxycycline; Dronabinol; Droperidol; Dyclonine; Eletriptan; Enalapril; Enoxaparin; Ephedrine; Epinephrine; Ergotamine; Etomidate; Famotidine; Felodipine; Fentanyl; Fexofenadine; Fluconazole; Fluoxetine; Fluphenazine; Flurbiprofen; Fluvastatin; Fluvoxamine; Frovatriptan; Furosemide; Ganciclovir; Gold sodium thiomalate; Granisetron; Griseofulvin; Haloperidol; Hepatitis B Virus Vaccine; Hydralazine; Hydromorphone; Insulin; Ipratropium; Isradipine; Isosorbide Dinitrate; Ketamine; Ketorolac; Labetalol; Levorphanol; Lisinopril; Loratadine; Lorazepam; Losartan; Lovastatin; Melatonin; Methyldopa; Methylphenidate; Metoprolol; Midazolam; Mirtazapine; Morhpine; Nadolol; Nalbuphine; Naloxone; Naltrexone; Naratriptan; Neostgmine; Nicardipine; Nifedipine; Norepinephrine; Nortriptyline; Octreotide; Olanzapine; Omeprazole; Ondansetron; Oxybutynin; Oxycodone; Oxymorphone; Oxytocin; Phenylephrine; Phenylpropanolaimine; Phenytoin; Pimozide; Pioglitazone; Piroxicam; Pravastatin; Prazosin; Prochlorperazine; Propafenone; Prochlorperazine; Propiomazine; Propofol; Propranolol; Pseudoephedrine; Pyridostigmine; Quetiapine; Raloxifene; Remifentanil; Rofecoxib; repaglinide; Risperidone; Rizatriptan; Ropinirole; Scopolamine; Selegiline; Sertraline; Sildenafil; Simvastatin; Sirolimus; Spironolactone; Sufentanil;

Sumatriptan; Tacrolimus; Tamoxifen; Terbinafine; Terbutaline; Testosterone; Tetanus toxoid; THC Tolterodine; Triamterene; Triazolam; Tricetamide; Valsartan; Venlafaxine; Verapamil; Zaleplon; Zanamivir; Zafirlukast; Zolmitriptan; Zolpidem; and combinations thereof.

13. The method of claim 1 wherein the one or more pharmaceuticals are present in a combined amount of up between about 0.005 wt.% and about 20 wt.% of the mucoadhesive film.

14. The method of claim 1 wherein the mucoadhesive film has a thickness of between about 0.1 mm to about 0.5 mm.

15. The method of claim 1 wherein the mucoadhesive film further includes a pharmaceutically acceptable dissolution-rate-modifying agent, a pharmaceutically acceptable disintegration aid, a pharmaceutically acceptable plasticizer, a pharmaceutically acceptable coloring agent, a pharmaceutically acceptable opaquifier, a pharmaceutically acceptable anti-oxidant, a pharmaceutically acceptable film forming enhancer, a pharmaceutically acceptable preservative, a component that acts to adjust the kinetics of the erodability of the mucoadhesive film, or a combination thereof.

16. The method of claim 1 wherein the mucoadhesive film further includes a third layer located between the water-soluble bioadhesive layer and the water-soluble

non-adhesive backing layer; wherein the third layer is flexible, biodegradable, bioerodible in tear fluids, and water-soluble.

17. The method of claim 1 wherein the pharmaceutical is locally delivered.

18. The method of claim 1 wherein the pharmaceutical is systemically delivered.

19. A method for locally delivering a pharmaceutical via an ocular surface of a mammal, the method comprising contacting the ocular surface of the mammal with a mucoadhesive film that comprises:

a water-soluble bioadhesive layer to be placed in contact with an ocular surface, the bioadhesive layer including one or more bioadhesive polymers and/or one or more film-forming, water-soluble polymers;

a water-soluble non-adhesive backing layer that comprises one or more water-soluble, film-forming, pharmaceutically acceptable polymers; and

one or more pharmaceuticals associated with the bioadhesive layer, associated with the non-adhesive layer, or associated with both the bioadhesive and non-adhesive layers;

wherein the mucoadhesive film is compatible with ocular surfaces; the mucoadhesive film adheres to ocular surfaces; the mucoadhesive film is flexible; and the mucoadhesive film is water-soluble, biodegradable, and bioerodible in tear fluids.

20. A method for systemically delivering a pharmaceutical via an ocular surface of a mammal, the method comprising contacting the ocular surface of the mammal with a mucoadhesive film that comprises:

a water-soluble bioadhesive layer to be placed in contact with an ocular surface, the bioadhesive layer including one or more bioadhesive polymers and/or one or more film-forming, water-soluble polymers;

a water-soluble non-adhesive backing layer that comprises one or more water-soluble, film-forming, pharmaceutically acceptable polymers; and

one or more pharmaceuticals associated with the bioadhesive layer, associated with the non-adhesive layer, or associated with both the bioadhesive and non-adhesive layers;

wherein the mucoadhesive film is compatible with ocular surfaces; the mucoadhesive film adheres to ocular surfaces; the mucoadhesive film is flexible; and the mucoadhesive film is water-soluble, biodegradable, and bioerodible in tear fluids.